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10/520,672	01/10/2005	Peter William Dettmar	102792-378 (P11085)	9407
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NORRIS, MCLAUGHLIN & MARCUS			FLOOD, MICHELE C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/520,672	DETTMAR ET AL.
	Examiner Michele Flood	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 22 May 2007.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-20 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 1/10/2005.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of the species polyoxyethylene-based surfactants as it reads on Claim 6; the absence of polyvinyl pyrrolidone as it reads on Claims 16 and 20; the absence of isopropyl alcohol as it reads on Claim 17; the absence of a granulating agent as it reads on Claim 18; and the absence of solvents as it reads on Claim 16 in the reply filed on May 22, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-20 are under examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are uncertain because it is unclear as to the identification of the ingredients to which Applicant intends to direct the subject matter.

Although the use of common names or traditional/ethnopharmacological names is permissible in patent applications, the standard Latin genus-species name of each ingredient should accompany non-technical nomenclature as a means for identifying the subject botanical matter noted in this application. Applicant may overcome the rejection by placing the genus-species name of "ispaghula" in parentheses after the term. Please make sure to write the Latin name in the proper format, wherein the first word is capitalized, the second word is lowercase and the entire name is italicized.

Claim 3 recites the limitation "the particle size" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the silica is" in line 2; and, inserting silica has a, before "particle" in line 2.

Claim 4 recites the limitation "the specific surface area" in line 2. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "the silica is" in line 2; and, inserting silica has a, before "specific" in line 2.

Claim 14 recites the limitation "the step of blending" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by replacing "the" with a.

Regarding Claims 16-18, the phrase, "preferably without the employment of 'X'", renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim 15 provides for “an ingestible composition or its manufacture substantially as described herein”, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a manufacture of a composition “substantially as described herein”, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Objections

Claim 2 is objected to because of the following informalities: With regard to Claim 2, line 1, there is an apparent omission of a verb in the sentence. Applicant may overcome the objection by is after “composition”, in line 1 of Claim 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-12 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chicouri et al. (N).

Applicant claims an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant wherein said composition is in a form so that in use it is dispersed in a liquid prior to ingestion. Applicant further claims an ingestible composition according to claim 1 wherein said composition in particulate or granular form; wherein the silica is present in an amount of between 0.01wt% and 5 wt% of the total weight of the ingestible composition; and, wherein the ingestible surfactant is a polyethylene-, polypropylene-, or polyoxyethylene-based surfactant. Applicant further claims an ingestible composition according to claim 6 wherein the polyethylene-based surfactant is a polyethylene glycol; wherein the polyoxyethylene-based surfactant is a polyoxyethylene sorbitan fatty acid ester; and, wherein the surfactant is a polyoxyethylene monostearate or a glycerol poly-ethylene glycol oxystearate. Applicant further claims an ingestible composition according to claim 1, wherein the ingestible surfactant is present in an amount of between 0.01 wt% and 5wt% of the total weight of the ingestible composition. Applicant further claims the composition according to claim

11 wherein the ingestible surfactant is polyethylene glycol and is present in an amount of between 0.1 wt% and 2wt% of the total weight of the ingestible composition.

Applicant claims a method of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant. Applicant claims an ingestible composition or its manufacture substantially as described herein. Applicant further claims a method according to claim 14, of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant preferably without the employment of any solvent. Applicant further claims a method according to claim 16, of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant preferably without the employment of isopropyl alcohol. Applicant further claims a method according to claim 14, of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant preferably without the employment of any granulating agent. Applicant claims further claims a method according to claim 18, of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible without the employment of polyvinyl pyrrollidone. Applicant further claims a method according to

claim 14, of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant without the employment of any solvent; and without the employment of any granulating agent.

Chicouri teaches an ingestible composition comprising ispaghula (Poudre de téguments de *Psyllium*) and colloidal silica (Silice colloïdale), on page 4, line 3 to line 10.

The teachings of Chicouri are set forth above. Chicouri teaches the instantly claimed composition and method of making thereof except for the ingredient of a surfactant. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to the composition and method of making thereof taught by Chicouri to provide the instantly claimed invention because Chicouri teaches that a surfactant having the claim-designated range of molecular weights, such as propylene glycol (propylène glycol), dipropylene glycol (dipropylène glycol) or trihydroxy propane, as well as polyoxyethylene-based surfactants, can be added to the active ingredients of the reference mixture in the making of an ingestible composition that is in a form so that in use it is dispersed in a liquid prior to ingestion. Chicouri further teaches that the amount of the surfactants added in the preparation of the reference composition should be in an amount such that it allows ingestion of the solution. See page 3, lines 1-22 and page 5, lines 1-10. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed surfactants to the

composition taught by Chicouri to provide the instantly claimed composition and method of making thereof because Chicouri teaches the requisite ingredients and process steps necessary to provide an ingestible composition in particulate or granular form comprising ispaghula, colloidal silica and an ingestible surfactant, so that in use the active ingredients are dispersed in a liquid prior to ingestion.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed composition and method of making thereof because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As the reference indicates that the various proportions and amounts of the ingredients used in the claimed composition, as well as the experimental parameters for the manufacturing thereof, are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by Chicouri.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chicouri et al. (N) in view of Palkhiwala et al. (A*).

Applicant's claimed invention of Claims 1, 2, 5-12 and 14-20 was set forth above.

Applicant further claims the composition of claim 1, wherein the particle size of the silica is between 5nm and 5 μ m; and, wherein the specific surface area of the silica is between 50 and 400 gm^{-2} . Applicant further claims the composition according to claim 11, wherein the surfactant is a polyoxyethylene sorbitan fatty acid ester and is present in an amount of between 1 wt% and 2 wt% of the total weight of the ingestible composition.

The obvious teachings of Chicouri are set forth immediately above. It is not clear from the obvious teachings of Chicouri the particle size and the specific surface area of the colloidal silica used in the making of the composition and the method of making thereof taught by Chicouri. Thus, the obvious teachings of Chicouri teach the instantly claimed inventions except for wherein the silica has a particle size of between 5nm and 5 μ m; wherein the specific surface area of the silica is between 50 and 400 gm^{-2} ; and, wherein the surfactant is a polyoxyethylene sorbitan fatty acid ester and is present in an amount of between 1 wt% and 2 wt% of the total weight of the ingestible composition. However, it would have been obvious to one of ordinary skill in the art to add a colloidal

silica having the claim-designated physical properties and to add the claim-designated surfactant to the composition and method of making thereof taught by Chicouri to provide the instantly claimed invention because at the time the invention was made the instantly claimed ingredients were known in the art as being useful in the making of an ingestible composition in particulate or granular form having the functional effect of being easily dispersible in a liquid prior to ingestion, as evidenced by the teachings of Palkhiwala. For instance, Palkhiwala teaches a powder composition comprising dietary bulk fibers, such as husks of grain or psyllium powder (see abstract; column 3, lines 24-34; and examples 2 & 4), coated with a surfactant. Surfactants comprising the composition taught by Palkhiwala include sorbitan esters and polyoxyethylene sorbitan fatty acid esters or polysorbates. In Column 4, lines 5-18, Palkhiwala teaches:

"Examples of useful polysorbates include polyoxyethylene 20 mono- and diglycerides of saturated fatty acids, polyoxyethylene 4 sorbitan monostearate, polyoxyethylene 20 sorbitan tristearate, polyoxyethylene 20 sorbitan monooleate, polyoxyethylene 5 sorbitan monooleate, polyoxyethylene 20, sorbitan trioleate, sorbitan monopalmitate, sorbitan monolaurate, propylene glycol monolaurate, glycerol monostearate, diglycerol monostearate, glycerol lactyl-palmitate. Most preferably, the surfactant is polyethylene 20 sorbitan monooleate or Polysorbate 80 (TWEEN 80 available from ICI Americas, Inc.).

The surfactant is typically present in the amount of from about 0.05 to 1.5 percent by weight of the total composition. More preferably, the composition comprises from about 0.1 to 0.9 percent by weight surfactant."

The composition further comprises other excipients, including colloidal silicon dioxide having the claim-designated particle size and specific surface area, e.g., AEROSIL® or AEROSIL 200®. See Column 4, lines 62-65. The amount of psyllium is greater than 50%, such as about 59% (Column 5, lines 18-19; examples 2 and 4); and, the amount of colloidal silicone dioxide is from about 1% to 8% (Column 4, lines 29-35). Palkhiwala also teaches a method for preparing the reference powder composition comprising dry

blending the bulking agent, surfactants and excipients, in Column 5, lines 8-28. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add a colloidal silica having the claim-designated physical properties and to add the claim-designated surfactant to the composition and method of making thereof taught by Chicouri to provide the instantly claimed invention because Palkhiwala teaches that the addition and continuous blending of an effective amount of surfactants, such as polyethylene glycol, polyoxyethylene monostearate, glycerol polyethylene glycol oxystearate, and a polyoxyethylene sorbitan fatty ester, as well as the addition of an effective amount of a colloidal silicon, such as AEROSIL® or AEROSIL 200®, having a particle size between 5nm and 5 μ m and a specific surface area of between 50 and 400 gm^{-2} with a bulking agent, such as the ingestible ispaghula or psyllium powder taught by Chicouri, provides for the making of a powder composition which is both readily dispersible in other granulated powders or a liquid such as water without clumping; moreover, like Chicouri, Palkhiwala teaches the desirability to obtain a psyllium composition that has improved mixability and dispersibility in a liquid. Thus, with regard to Claim 13 wherein Applicant claims a composition having claim-designated percent amounts of the surfactant polyoxyethylene sorbitan fatty acid ester, it would have been merely a matter of judicious selection for one of ordinary skill in the art at the time the invention was made to pick and choose any of the instantly claimed surfactants or to replace the surfactant used in the method taught by Chicouri for the polyoxyethylene sorbitan fatty acid ester

taught by Palkhiwala because Palkhiwala suggests that the claim-designated surfactants are functional equivalents, each one for the other.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the claimed ingredients in the making of the claimed composition and method of making thereof because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As the references indicate that the various proportions and amounts of the ingredients used in the claimed composition, as well as the experimental parameters for the manufacturing thereof, are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web

site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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MCF
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